



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,881	04/18/2000	WILLIAM IAN DAVID	9267.8	6916

23973 7590 07/01/2002

DRINKER BIDDLE & REATH
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 07/01/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/463,881

Applicant(s)
David et al.

Examiner
Ardin Marschel

Art Unit
1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 18, 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- ~~4b) Of the above~~, claim(s) 12-20 have been canceled is/are ~~withdrawn from consideration~~.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Apr 18, 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Applicants' arguments, filed 4/18/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The Abstract of the Disclosure, submitted 4/18/02, is objected to because it is too long. It must be limited to 150 words. Applicants are reminded that a new abstract must be submitted on its own separate sheet of paper. Correction is required. See M.P.E.P. § 608.01(b).

Claims 1-11 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature

of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is maintained and reiterated from the previous office action, mailed 9/12/01. Applicants firstly acknowledge that the complications of structure factor analysis that is used to drive the covariance matrix of the instant invention would be known to those skilled in the art as evidenced by a workshop paper delivered in 1999. This acknowledgment, however, is confusing because no such workshop paper copy is attached to the REMARKS, filed 4/18/02. Such a paper, however, may be pertinent to the examination of this application and a copy is hereby requested for consideration under applicants' duty to disclose such documents. Applicants then argue regarding convergent versus divergent series in that the threshold discussed at page 19, lines 16-19 has the sole purpose to terminate the iterative process. Consideration of said page 19 citation reveals that this is a citation from instant claim 1 wherein there is no discussion of this "sole purpose". Thus, it

is still unpredictable whether the claimed process will diverge or converge. It is noted that applicants argue that Figures 6 and 7b show improvement in the fitness followed by a leveling off. It is not seen how two examples which perform well relates to the predictability of convergence versus divergence. There is therein no indication of what generic results would produce. No probability of success or convergence. No calculation with a variety of crystals as to the predictability of convergence. Without some calculated prediction or probability of success a complex series of iterative algorithm steps has no predictability of convergence versus divergence. If someone were to perform a throwing of dice and obtain two 7/11 results in a row, this type of success lacks any indication of what the next throw would produce. It, however, is noted that it is well known how to calculate the probabilities for various results of a throw of the dice. It is noted and is confusing as to why applicants have not also set forth such a calculation or reasoned estimate for their invention in response to this rejection. This leaves the concern still an issue as to the unpredictability of the performance of applicants' invention result.

This rejection is maintained and reiterated from the previous office action, mailed 9/12/01. Applicants then argue that the "predetermined threshold" as an optimum threshold value must be determined for each crystal and that is easily within the

ability of the skilled person. This ease/ability is an allegation without factual support and thus non-persuasive. This rejection is therefore maintained and reiterated from the previous office action, mailed 9/12/01.

The rejection based on the lack of enablement of regarding "predetermined unit cell and space group" is hereby withdrawn.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the fitness formula calculation in claim 5 (subject to the certain lack of enablement issues regarding the claim 5 formula itself), does not reasonably provide enablement for generic fitness calculation as in claims 1-4 and 6-11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the

relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is maintained and reiterated from the previous office action, mailed 9/12/01. Applicants argue that generic fitness evaluations may be performed as listed, for example, in the specification on page 12, lines 10-16. These evaluations are therefore essential subject matter to broaden the fitness practice beyond that of claim 5. It is noted that these essential subject matter methods have not been instantly explained nor has applicants set forth any factual evidence as to the manner of evaluating fitness with these functions. Such an allegation without factual support is non-persuasive. It is suggested that, if applicants wish to establish these fitness functions as being well known in the art for fitness calculation, then supplying more than allegations is required, such as submission of a plurality of documents or textbook chapters etc. to support such allegations. If these fitness calculation functions are well known in the art, the supplying of such documentation should be easily accomplished. It is additionally

noted that the cited functions lack any disclosure of fitness evaluation. For example, the first cited function is the simultaneous fitting of both X-ray and neutron diffraction data. How does this produce a fitness? Also, the trial structures are expected to be in silico, and thus unavailable for any diffraction data determination. The next function is that of molecular packing. It is not understood what fitness is determinable by evaluating packing. The issue is fitness and not how packed a molecule is. These same concerns are equivalently applicable to the other functions in said page 12 citation. In summary, the arguments of applicants are non-persuasive regarding this rejection.

This rejection is maintained and reiterated from the previous office action, mailed 9/12/01. Additionally, the evaluation of the claim 5 formula has not been set forth so as to enable variable evaluation, which is the basis for this rejection as reiterated and maintained from the previous office action, mailed 9/12/01. Applicants again allege that this is within the skill in the art but without any supporting factual evidence. For example, the formula in claim 5 cites I_h , I_k , F_h , and F_k but only gives a "name" for $I_{h,k}$ and $F_{h,k}$ and also does not even name I_h , I_k , F_h , and F_k as in the formula. It is also noted that the evaluation of parameter "c" in the formula is only discussed on page 11, lines 15-18, without any concept set forth as to what is

optimized or what calculation or parameter points to the optimized value for "c". A least squares analysis is cited but without defining what factors and reduced data is meant. Are all the factors utilized with all the reduced data or some undefined subset? No other discussion or guidance as to "c" evaluation has been found in the instant specification. Thus, total experimentation is required to find "c" which is deemed undue experimentation.

The citation of Wormington et al. (P/N 6,192,103) is listed on the enclosed PTO 892 as being of interest regarding evolutionary algorithms as applied to X-ray scattering data from various materials including crystals and powdered samples.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

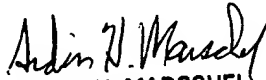
(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 28, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER